REMARKS

Claims 1, 3, 7-20, 22, and 37 are pending in the application. Claims 1 and 13 have been amended. Support for the amendments can be found in the specification at, e.g., page 5, lines 17-27. These amendments add no new matter.

35 U.S.C. § 112, First Paragraph (Written Description)

At pages 2-5 of the Office Action, claims 1, 7-11, 14-20, 22, and 37 were rejected as allegedly containing subject matter that was not described in the specification in such a way that one skilled in the art can reasonably conclude that the inventors, at the time the application was filed, had possession of the claimed invention. According to the Office Action, "the specification only describes two proteins of the recited genus and fails to teach or describe any other protein which meets the limitation of mammalian aggregate-prone amyloid protein."

Applicant respectfully traverses the rejection in view of the claim amendments and the following remarks.

Amended independent claim 1 is directed to a method of identifying a candidate substance that inhibits aggregation of a mammalian aggregate-prone amyloid protein in a yeast cell. The claimed method includes the following steps: (a) contacting a yeast cell that expresses a chimeric protein comprising a mammalian aggregate-prone amyloid protein with a candidate substance under conditions effective to allow aggregated amyloid formation in the yeast cell; and (b) determining the ability of the candidate substance to inhibit the aggregation of the aggregate-prone amyloid protein in the yeast cell.

As detailed in the specification, a "mammalian aggregate-prone amyloid protein" is a mammalian protein that is able to form an amyloid or amyloid-like deposit (see specification at page 5, lines 17-23). The present application describes prion protein (PrP) and β-amyloid as two examples of mammalian aggregate-prone amyloid proteins (see specification at page 5, line 22). However, in addition to PrP and β-amyloid, the person of ordinary skill at the time the application was filed was aware that numerous other proteins are also able to form amyloid or amyloid-like deposits. As detailed in the enclosed publication of Ross et al. (2004) *Nature*

Medicine 10 Suppl:S10-7 ("Exhibit A"), several neurodegenerative diseases are characterized by the formation of protein aggregates (termed "amyloid") that consist of fibers containing misfolded protein with a β-sheet conformation. Exhibit A lists examples of several specific proteins that form amyloid deposits in particular disease states. In addition to PrP and β-amyloid, Exhibit A also describes other amyloid forming proteins including huntingtin, atrophin-1, ataxins, androgen receptor, tau, and α-synuclein. The person of ordinary skill in the art would understand these well characterized proteins to be encompassed by the generic claim term "mammalian aggregate-prone amyloid protein." In addition, the "aggregate forming domain" (as that term is used in claim 7) of a given aggregate-prone amyloid protein is generally known or easily determined by the skilled person by use of routine assays that identify the region of a protein required for aggregation.

The Office Action stated that "[t]he specification does not provide a complete structure of those polypeptides that are mammalian aggregate-prone amyloid proteins and fails to provide a representative number of species for the recited genus." However, an adequate written description of a biological macromolecule need not contain recitation of a sequence or structure that is already known in the art. See, e.g., Falkner v. Inglis, 448 F.3d 1357 (Fed. Cir. 2006); Capon v. Eshar, 418 F.3d 1349 (Fed. Cir. 2005) (vacating and remanding the Board's holding of unpatentability of several claims of U.S. Patent Number 6,407,221, claim 1 of which recites *inter alia* a "DNA encoding a signal sequence which directs said membrane bound protein to the surface membrane"). The large number of mammalian proteins that were known in the art to form amyloid or amyloid-like deposits are representative of the full scope of the genus encompassed by the term "mammalian aggregate-prone amyloid protein." Because these proteins were known by the skilled artisan to be aggregate-prone amyloid proteins, they need not be repeated in the specification to support the use of the generic term in the claimed methods.

In view of the foregoing, the skilled artisan would have concluded that the inventor was in possession (at the time of filing of the present application) of the necessary common attributes possessed by the members of the genus recited in the claims. As a result, applicant requests that the rejection be withdrawn.

35 U.S.C. § 112, Second Paragraph (Indefiniteness)

At pages 6-7 of the Office Action, claims 1, 3, 7-20, 22, and 37 were rejected as allegedly indefinite.

The Office Action stated that claim 1 is vague and indefinite in its recitation of the terms "mammalian aggregate-prone amyloid protein" and "mammalian aggregate-prone amyloid peptide." Claim 1 has been amended to recite a "chimeric protein comprising a mammalian aggregate-prone amyloid protein." PrP and β-amyloid are described in the specification (at page 5, lines 17-23) as examples of mammalian aggregate-prone amyloid proteins. The term "mammalian aggregate-prone amyloid peptide" has been deleted from the claims. It is applicant's understanding that the amendment overcomes the rejection of claim 1 and the claims that depend therefrom.

The Office Action stated that claim 13 is vague and indefinite in its recitation of "about amino acids 1-42." Claim 13 has been amended to remove the term "about," thereby obviating the present rejection.

CONCLUSIONS

Applicant submits that all grounds for rejection have been overcome, and that all claims are in condition for allowance, which action is requested.

Enclosed is a Petition for Three Month Extension of Time. The extension of time fee in the amount of $525 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 17481-004001.

Respectfully submitted,

Date: October 1, 2007

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